K060528

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Craniofacial Plate & Screw System
24 February 2006

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Matthew M. Hull
800-258-1946 (phone)
610-791-6882 (fax)
matt.hull@aesculap.com (email)

TRADE NAME: Trelon® Polyamide Multifilament Nonabsorbable Suture

COMMON NAME: Polyamide Nonabsorbable Suture

CLASSIFICATION NAME: Suture, Nonabsorbable, Synthetic, Polyamide

REGULATION NUMBER: 878.5020

PRODUCT CODE: GAR

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Trelon® sutures described here are substantially equivalent to the Dafilon® sutures previously cleared in the Aesculap Premarket Notification #K990090.

DEVICE DESCRIPTION

The Trelon® sutures are a polyamide (Nylon) multifilament suture that is available in common sizes and lengths and is available with or without pre-attached needles.

INDICATIONS FOR USE

Trelon® sutures are intended for use in general and soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Trelon® sutures use the exact same material polyamide (Nylon 6.6) as the predicate Dafilon® device with only difference being that the new device is a multifilament suture as opposed to monofilament. As with other multifilament sutures the Trelon® also uses as silicon coating.

PERFORMANCE DATA

The Trelon® sutures meet all USP requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2006

Aesculap® Inc.
c/o Matthew M. Hull
3773 Corporate Parkwayental Projects
Center Valley, PA 18034

Re: K060528
Trade/Device Name: Trelon Polyamide Sutures
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable polymade surgical suture
Regulatory Class: II
Product Code: GAR
Dated: February 24, 2006
Received: March 1, 2006

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K060528

Device Name: Trelon Polyamide Sutures

Indications for Use:

Trelon® sutures are intended for use in general and soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic, and neurological procedures.

Prescription Use X and/or Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060528